

Sheet 1 of 4

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Application Number	10/616,692
Filing Date	07/09/2003
First Named Inventor	NELSON, Jodi
Art Unit	1614
Examiner Name	Royds, Leslie A.
Attorney Docket Number	47-00B

Confirmation No. 1639

GWS 11/12/08

U.S. PATENT DOCUMENTS

Examiner Initial*	Cite No.	Patent Number	Issue Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
/J.C./	1	5,314,894	05/24/1994	Stecher et al.	

U.S. PATENT APPLICATION PUBLICATIONS

Examiner Initial*	Cite No.	Publication Number	Publication Date (MM-DD-YYYY)	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear
-------------------	----------	--------------------	-------------------------------	---	--

FOREIGN PATENT DOCUMENTS

Examiner Initial*	Cite No.	Foreign Document Number	Country Code	Publication Date (MM-DD-YYYY)	Name	Pages, Columns, Lines where Relevant Passages or Relevant Figures Appear	T ⁵
	2	WO 01/03649	WO	01/18/2001	Nelson	No copy provided	

NON-PATENT LITERATURE DOCUMENTS

Examiner Initial*	Cite No.	REFERENCE	T ⁵
		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	
/J.C./	3	ABBOTT, N.J. et al., "Transporting therapeutics across the blood-brain barrier" Molecular Medicine Today, March 1996, Vol. 2, Issue 3, pp. 106-113	
	4	"ARALEN® CHLOROQUINE PHOSPHATE, USP" (2001), Aralen® package insert text downloaded November 13, 2007 from www.fda.gov/cder/foi/label/2003/06002sl039_aralen_lbl.pdf , pgs. 4,26.	
	5	BRANSKI et al., "Effect of Cimetidine on Human Gastric and Duodenal Prostanoid Synthesis," <i>Scand J Gastroenterol</i> , 1984, 19(4), pp.457-460.	
	6	"Carbidopa/levodopa" Micromedex Healthcare Series, http://micromedex.uchsc.edu/mdxcgi/quicklocn.exe?CT	No Copies provided
	7	Chloroquine downloaded from the Inchem database of the International Programme on Chemical Safety (IPCS), at http://www.inchem.org/documents/pims/pharm/chloroqu.htm . Pgs. 1, 7 and 9.	

Examiner Signature	/Jean Cornet/	Date Considered	09/09/2008
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Application Number	10/616,692
Filing Date	07/09/2003
First Named Inventor	NELSON, Jodi
Art Unit	1614
Examiner Name	Royds, Leslie A.
Attorney Docket Number	47-00B

Confirmation No. 1639

GWS 11/12/08

Examiner Initial*	Cite No.	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	8	CHLOROQUINE downloaded from the MICROMEDEX® Interactions Table on July 24, 2008.	
	9	EINARSON, T. R. et al. (1985) "Gout-like arthritis following cimetidine and ranitidine", Drug Intell. Clin. Pharm 19(3):201-202	
	10	ETTE, E.I. et al. (1987), "Chloroquine Elimination in Humans: Effect of Low-Dose Cimetidine," J. Clin. Pharmacol. 27:813-816.	
	11	FINK et al., "Chloroquin-Enantiomere," 1979, pp.163-164.	
	12	GOTO, M. et al. (2001), "Intra-articular injection of hyaluronate (SI-6601D) improves joint pain and synovial fluid prostaglandin E2 levels in rheumatoid arthritis: A multicenter clinical trial," Clin. And Exp. Rheumatol. 19:377-383	
	13	"Guidance for Industry" (November 1999), downloaded from FDA website, pg.13	
	14	HABERKORN et al., "Antimalarial Activity in Animals of the Optical Isomers of Chloroquine Diphosphate," Tropenmed. Parasit. 1979, 31, pp.308-312.	
	15	"Histamine H ₂ Antagonists," Drug Facts & Comparisons, Mar 2002, pp.1129-1130. No copies	
	16	IREDA, R. et al., CHARACTERISTICS OF HYDROXYCHLOROQUINE: Determination of the Stereoisomers of Hydroxychloroquine and Its Major Metabolites in Plasma and Urine Following a Single Oral Administration of Racemic Hydroxychloroquine," Seminar in Arthritis and Rheumatism, 1993, 23, pp.74-81.	
	17	KHONG, T.K. and Rooney, P.J. (1980), "Arthritis Associated with Cimetidine," Lancet 2:9208-8209):1380.	
	18	MANGER, B.F. et al. (1983) "Cimetidine and psoriatic arthritis" Arch. Dermatol. 119(10):792.	
	19	MIEKENS et al., "Effects of Disease Modifying Antirheumatic Drugs and Nonsteroidal Antiinflammatory Drugs Upon Cellular and Fibronectin Responses in a Pleurisy Model," J Rheumatol, 1985, 12, pp.1083-1087.	
	20	MINE et al., "Healing of Chronic Gastric Ulcer Depends on Gastric Mucosal Prostaglandin Synthesis," Hepato-Gastroenterol, 1994, 41, pp.111-115.	
	21	MUSTAPHA et al., "Effects of cimetidine on the absorption kinetics of chloroquine," African Journal of Pharmacy & Pharmaceutical Sciences, 1993, 23(1), pp.51-54.	

Examiner Signature	/Jean Cornet/	Date Considered	09/02/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Application Number	10/616,692
Filing Date	07/09/2003
First Named Inventor	NELSON, Jodi
Art Unit	1614
Examiner Name	Royds, Leslie A.
Attorney Docket Number	47-00B

Confirmation No. 1639

GW5 11/12/08

Examiner Initial*	Cite No.	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	22	NIVAQUINE ® downloaded from MEDSAFE , New Zealand Medicines and Medical Devices Safety Authority, a business unit of the Ministry of Health, at http://www.medsafe.govt.nz/profs/Datasheet/n/Nivaquininetabssr.htm	
	23	NOTOYA, et al. (2000) "The Induction of Cell death in Human Osteoarthritis Chondrocytes by Nitric Oxide is Related to the Production of Prostaglandin E ₂ Via the Induction of Cyclooxygenase-2", J. Immunology, 3402-3410	
	24	ONEREKE, C.S., (1999) "Management of HIV-Infected Pregnant Patients in Malaria-Endemic Areas: Therapeutic and Safety Considerations in Concomitant Use of Antiretroviral and Antimalarial Agents" Clinical Therapeutics 21(9):1456-1496.	
	25	PACIFICI, G.M. et al. (1992), "Histamine N-methyl transferase:inhibition by drugs," Br. J. Clin Pharmacol. 34(4):322-327.	
	26	Physician's Desk Reference for the year 2000, entry for Aralen®, pp. 2734-2735	
	27	Physician's Desk Reference (PDR) for 2000, the entry for Tagamet brand of cimetidine, pp. 3043-3046	
	28	ROBINSON et al., "Prostaglandin-Stimulated Bone Resorption by Rheumatoid Synovia," The Journal of Clinical Investigation, 56, 1975, pp.1181-1188.	
	29	SHARON et al., "Prostanoid Synthesis by Cultured Gastric and Duodenal Mucosa: Possible Role in the Pathogenesis of Duodenal Ulcer," Scan J Gastroenterol, 1983, 18, pp.1045-1049.	
	30	SHEIBANIE, A.F. et al. (2007), "Prostaglandin E ₂ Exacerbates Collagen-Induced Arthritis in Mice Through the Inflammatory Interleukin-23/Interleukin-17 Axis," Arthritis & Rheumatism 46(8):2608-2619.	
	31	"Sterling Drug" (October 11, 2007), Wikipedia, downloaded from http://en.wikipedia.org/wiki/Sterling_Drug on January 20, 2008.	
	32	STOCKLEY, Ivan H. (1999) "Drug Interactions, A Source Book of Adverse Interactions, Their Mechanisms, Clinical Importance and Management" 5 th Ed., pg.131.	
	33	SUGIYAMA et al., "Interleukin-4 inhibits protaglaglandin E ₂ production by freshly prepared adherent rheumatoid synovial cells via inhibition of biosynthesis and gene expression of cyclo-oxygenase II but not of cyclo-oxygenase I," Annals of the Rheumatic Diseases, 1996, 55, pp.375-382.	

Examiner Signature	/Jean Cornet/	Date Considered	09/02/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. *Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

Application Number	10/616,692
Filing Date	07/09/2003
First Named Inventor	NELSON, Jodi
Art Unit	1614
Examiner Name	Royds, Leslie A.
Attorney Docket Number	47-00B

Confirmation No. 1639

GWS 11/12/08

Examiner Initial*	Cite No.	REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁵
	34	TETT et al., "A dose ranging study of the pharmacokinetics of hydroxy-chloroquine following intravenous administration to healthy volunteers," <i>Dr. J. Clin. Pharmac.</i> , 1988, 26, pp.303-313.	
	35	WAINER et al., "Distribution of the Enantiomers of Hydroxychloroquine and Its Metabolites in Ocular Tissues of the Rabbit After Oral Administration of Racemic-Hydroxychloroquine," <i>Chirality</i> , 1994, 6, pp.347-354.	
	36	WISELOGLE, ed., "A Survey of Antimalarial Drugs," 1946, 1, pp.388-390.	
	37	YAMAUCHI, K., et al. (1994) "Structure and function of human histamine N-methyltransferase: critical enzyme in histamine metabolism in airway," <i>Am. J. Physiol. Lung Cell Mol. Physiol</i> 267:L342-L349.	
	38	ZUCCHERO et al. (Eds.) (2001) "Evaluations of Drug Interactions (EDI)" (Vol. I). St. Louis: First DataBank, Inc. Endorsed by APHA (the American Public Health Association). No copies provided	

Examiner Signature	/Jean Cornet/	Date Considered	09/02/2009
--------------------	---------------	-----------------	------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.